

BEFORE THE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MD 20852

REQUEST FOR COMMENTS ON
CONSUMER-DIRECTED PROMOTION OF REGULATED MEDICAL PRODUCTS

COMMENTS OF THE
NEWSPAPER ASSOCIATION OF AMERICA

FEBRUARY 17, 2006

February 17, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2005N-0354
Request for Comments: Consumer-
Directed Promotion of Regulated
Medical Products

I. Introduction and Summary

The Newspaper Association of America is pleased to submit these comments on Consumer-Directed Promotion of Regulated Medical Products. These comments focus on the Food and Drug Administration's guidance for broadcast and print direct-to-consumer (DTC) advertising.

NAA is the principal trade association for the newspaper industry, representing more than 2,000 newspapers in the United States and Canada. The association's membership accounts for nearly 90 percent of U.S. daily newspaper circulation. Many non-dailies are also members of NAA.

While not utilized as much as broadcast and magazines, newspapers are carrying a growing amount of prescription drug advertising. There are good reasons why advertisers are using newspapers to deliver prescription drug information. First,

newspapers are widely circulated. More than half of all adults read a daily newspaper every weekday and more than six in 10 adults read newspapers each Sunday. Second, newspapers allow advertisers to target advertisements to a particular audience or market. Third, newspapers, with their reach and immediacy, are uniquely suited to compliment a broadcast advertisement schedule to deliver the detailed information necessary for consumers to learn the disadvantages and advantages of prescription drugs so that they can more fully participate with their physicians in the decision making process.

NAA respectfully requests that the FDA recognize in a revised guidance for broadcast advertisements that newspapers are an appropriate means for advertisers to supplement broadcast advertising so that consumers who see or hear a broadcast advertisement for a prescription drug can have reasonably convenient access to more product information. Consumers who are passive information seekers, those who do not have access to the Internet and are reluctant to identify themselves as seeking information about prescription drugs, could have access through newspapers to additional risk and benefit information about prescription drugs that they have heard about in broadcast advertisements.

In addition, NAA requests that the FDA finalize its draft guidance for disclosure in consumer-directed print advertisements. The proposed alternatives for a shorter and clearer “brief summary” will make it easier for consumers to focus on the most important benefit and risk information without having to cut through a lengthy and complex presentation of information that is not helpful to them.

II. Value of Direct-To-Consumer Advertisements

The American market economy relies on the flow of truthful information between producers and consumers. Information about products allows consumers to make knowledgeable buying decisions, which communicate to product manufacturers consumer preferences and priorities. Such information sparks competition which generally leads to product improvements, innovations, and lower prices, all of which benefit consumers. Advertising also has the power to motivate positive behavior and encourage healthier lifestyle choices by merely providing information – such as information on diseases and their treatment.

Prescription drug advertising can inform consumers and raise awareness on important health issues. Advertising is a primary means of giving the public information that they can use to make decisions about their health care and may encourage consumers to see a physician about previously untreated health conditions.

Surveys conducted by the FDA (in 2002) and *Prevention* magazine (in 2004) demonstrate that DTC advertising has prompted between 23 and 30 million Americans to talk to a doctor about a condition for which they had not received prior medical care. According to a 2004 USA Weekend Magazine survey, 52 percent of readers surveyed had spoken to a doctor about a medication that was advertised. Fifteen percent of those patients discussed a condition that had not previously been diagnosed. The same study found that 52 percent of survey respondents agreed that pharmaceutical ads “help patients make informed health care decisions.”

As consumers increasingly participate in decisions regarding their health care, it is imperative that they have access to information about the products and treatment options available to them so that they can participate fully in a discussion with their physicians. Prescription drug advertising plays an important role in informing consumers about the

existence and nature of certain medical conditions and the availability of products to treat them. Such advertising allows consumers to decide if further inquiry is called for, and makes them aware of where additional information can be obtained.

III. Guidance for Broadcast Advertisements

Direct-to-consumer advertisements for broadcast and for print are treated very differently under current regulations. Existing FDA regulations require print advertisements for prescription drugs to include a “brief summary” of the product’s side effects, contraindications, and effectiveness. Broadcast advertising must contain a statement of the product’s major side effects and contraindications and must either make “adequate provision” for dissemination of the product’s package labeling or present a brief summary of the side effects and contraindications in the advertisement.

NAA generally supports the “Guidance for Industry on Consumer-Directed Broadcast Advertisements,” published in Aug. 1999, as a laudable effort to make broadcast advertising of prescription drugs a realistic option for advertisers. Given the limitations within the standard 30- or 60-second commercial format, the FDA’s guidance for broadcast advertisements outlines alternatives for meeting the “adequate provision” requirement. The time and space limitations inherent in broadcast do not lend themselves to being able to provide complete and important information on a prescription drug. However, it is important to note that broadcast DTC advertisements may have the power to alert consumers to a drug that is available and, ultimately, encourage consumers to have a conversation with their physician about a medical condition.

NAA believes the FDA should examine the effectiveness of the “adequate provision” requirement in its guidance for Consumer-Directed Broadcast Advertisements

to see if there is a way to enhance consumers' access to more detailed information on a prescription drug. More specifically, the FDA should reverse the implication, by silence in the guidance, that newspapers are not an appropriate mechanism to fulfill the requirements of "adequate provision."

The guidance for broadcast advertisements states that any mechanism for disseminating the product labeling must include methods calculated to reach people without access to sophisticated technology (such as the Internet or personal fax machine) and those who are reluctant to actively seek information about the product being advertised. The guidance suggests that broadcast advertisers can meet the "adequate provision" requirement through an approach that contains the following components:

- A. Disclosure in the advertisement of a toll-free telephone number for consumers to call for the approved package labeling;
- B. Reference in the advertisement to a mechanism to a concurrent print advertisement that contains additional product information or an alternative mechanism for providing private access to product information, such as "sufficient numbers of brochures containing package labeling in a variety of public accessible sites";
- C. Disclosure in the advertisement of an Internet web page (URL) address that provides access to the package labeling; and
- D. Disclosure of a statement in the advertisement that pharmacists, physicians, (or other healthcare providers) or veterinarians (in the case of animal drugs) may provide additional product information to consumers.

In the broadcast guidance, as well as in the questions and answers that were used to explain the guidance, the FDA focused on magazines as a vehicle for “adequate provision” which may have indicated that newspapers were not an appropriate vehicle as the print component of adequate provision. In short, the FDA’s guidance for consumer-directed broadcast advertisements does not take full advantage of the important characteristics of newspaper advertising to improve consumers’ access to significant information, particularly for those consumers who are passive information seekers.

The broadcast guidance emphasizes that, whatever method or combination of methods is chosen, it “should allow most of a potentially diverse audience” access to more product information. The guidance also emphasizes the method used should make it as easy as possible for consumers “with restricted access to sophisticated technology, such as the Internet, and those who are uncomfortable actively requesting additional product information or are concerned about being personally identified in their search to obtain the information.” The guidance also states that one mechanism for meeting the needs of these consumers is to provide additional information in the form of print advertisements “appearing concurrently in publications that reach the exposed audience.”

NAA believes newspaper advertising is uniquely suited to meet the above mentioned objectives, making sure that consumers who see or hear a broadcast advertisement for a prescription drug have reasonably convenient and concurrent access to more information on the benefits and risks of a product.

IV. Newspapers as a Vehicle for “Adequate Provision”

Newspapers make it easier for consumers to have access to more information about the risks and benefits of a prescription drug without having to identify themselves,

wait for a response, or go out of their usual way. Since many Americans receive newspapers by subscription and do not have to take any additional steps, like calling a 1-800 number, going out to purchase a magazine mentioned in a broadcast advertisement, or visiting the Internet, many consumers could have access to more detailed information on an advertised prescription drug – literally at their doorstep – with the delivery of their newspaper. Newspaper advertisements are also uniquely suited to provide immediacy and substantial detail in a form that is easily retained and referred back to by consumers, doctors and others that may be involved in important health care decisions.

At the same time, consumers view newspapers as a dependable and credible source for information. In a recent study¹, respondents ranked newspapers as the most trustworthy of the media, especially for providing “information that I trust” and for being a “very reliable source.” In fact, 42 percent of those surveyed said that newspapers have credible advertising, compared to 34 percent for television, 32 percent for magazines and 16 percent for the Internet.

In addition, both the widespread availability and the actual readership of newspapers seem to satisfy the need for reaching consumers commensurate with the broadcast advertisement. More than 50 percent of all adults read a daily newspaper every weekday and more 60 percent of adults read newspapers each Sunday. Online versions of newspapers also attract a large audience.

Advertisers often execute a campaign using multiple newspaper products such as the printed and online version of the newspaper. The simultaneous placement of advertisements in both the printed and online newspaper expands an advertiser’s ability

¹ “Newspapers are the New Media Connection,” released in September 2005. Millward Brown conducted the Newspaper National Network (NNN) Media Engagement Study in June 2005 via a web based interview of 3013 adults 18+ who read three or more issues of the newspaper in the past seven days. The sample was weighted to reflect US age proportions and was national in scope.

to reach a much broader audience in a concurrent fashion. More than 55 million people visited a newspaper Web site in November 2005. Furthermore, in 22 of the top 25 U.S. markets, newspaper Web sites reach more local Internet users than any other local site. With more than 1,500 North American dailies on the Internet, online readers have come to expect the same reliable information found in their traditional, hard-copy newspaper.

Advertisers also take advantage of newspaper services that provide “one order, one bill”² packages, matching newspapers with a television schedule to ensure that consumers who see or hear a broadcast advertisement are reasonably likely to be exposed to a print advertisement during the same period.

Similarly, these “one order, one bill” services can be used by advertisers in local and time-sensitive situations to provide consumers with more information about a prescription drug. For example, some manufacturers of flu drugs use Center for Disease Control (CDC) reports to track the occurrence of the flu virus as it appears around the country. As the CDC identifies local and regional areas experiencing an outbreak of the flu virus, companies – in a matter of days – are able to purchase spot TV to alert consumers to the availability of flu drugs. Because of the time-sensitive and local nature of this activity, national magazines are not a practical medium for reaching consumers in a local market with concurrent product information. Newspapers can be used – on short notice – by advertisers to provide a targeted, local audience with more detailed product information. In this example, an advertiser could refer viewers of the local broadcast advertisement “to your local Sunday newspaper” for more information on the advertised

² One of many organizations to provide this type of service is the Newspaper National Network (NNN). NNN was formed in 1994 by leading newspaper companies and the Newspaper Association of America. NNN works with advertisers and their agencies to find ways to make multi-market newspapers work in support of their marketing strategies. They plan and place ads in over 9,000 newspapers.

product. An advertisement that is placed in the Sunday edition of every daily newspaper in a market each week during the television flight, can closely resemble the local television plan in reach, frequency and total exposures.

NAA respectfully requests that the FDA recognize in a revised guidance for broadcast advertisements that newspapers are an appropriate vehicle for advertisers to utilize in supplementing broadcast advertising. By using newspapers to fulfill the adequate provision requirement, consumers who see or hear a broadcast advertisement for a prescription drug will have reasonably convenient access to more information about the effects of a prescription drug.

VI. Brief Summary for Print Advertisements

NAA supports the approach that the FDA has proposed in the draft guidance, “Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements,” published in Jan. 2004. The guidance allows for alternatives to the inclusion of the entire brief summary. As discussed in prior comments, the requirement that the brief summary be included in its entirety does not provide any substantial benefits to consumers or health care professionals in terms of useful and understandable information. The adoption of the draft guidance allowing for alternatives will allow newspaper DTC advertisements to continue to have vital information available, but written in a way that readers can more easily understand. Current brief summaries are lengthy, complicated presentations of the information generally found in prescription drug package inserts.

The proposed alternatives would enable readers to more easily focus on the safety of the drug without having to work through the extensive and complex medical

information currently required by the regulations. A short and clear statement of safety issues would be more useful to the average consumer. Readers would be better served by having a more concise description highlighting the drug's contraindications, warnings, precautions and adverse reactions.

The alternatives proposed in the draft guidance will still enable newspaper advertisements to provide consumers with more information than television or radio advertisements, but allows for it to be presented in a manner that is more consumer friendly.

IV. Conclusion

NAA believes that direct-to-consumer prescription drug advertising can serve a valuable purpose in educating consumers on their health care choices. NAA believes the FDA's guidance for broadcast advertisements does not promote all of the options available to advertisers to fulfill requirements for the "adequate provision." Since newspapers were overlooked in the 1999 guidance for broadcast advertisements, NAA encourages the FDA to acknowledge that newspapers are an appropriate and viable means for advertisers to provide consumers with more information in a concurrent and complimentary way to broadcast advertisements.

NAA also encourages the FDA to finalize its draft guidance for consumer-directed print advertisements. Adoption of the draft guidance on the brief statement would help newspapers continue to provide consumers with comprehensive information on the benefits and risks of prescription drugs while making it more user-friendly for the reader.

NAA appreciates the opportunity to comment and looks forward to working with the FDA and advertisers to fulfill the promise of more effective communication of risk information about prescription drugs.

Respectfully submitted,

A handwritten signature in dark ink, reading "Paul J. Boyle". The signature is fluid and cursive, with the first name "Paul" and last name "Boyle" clearly legible.

Paul J. Boyle
Senior Vice President/Public Policy
Newspaper Association of America
529 14th Street, N.W., Suite 440
Washington, DC 20045
202-783-4697
boylp@naa.org